

**K163315 Internal Distraction - Sterile**May 5, 2017  
163 days to decisionK163315 · Product code: **PBJ** · Neurology  
Source: <https://www.510kdatabase.net/k163315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Distraction System (PBJ)
Date received	Nov 23, 2016
Decision date	May 5, 2017
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KLS-Martin L.P.</b>
Location	Jacksonville, FL, US
Contact	Jennifer Damato
Website	<a href="https://www.klsmartin.com">https://www.klsmartin.com</a>
510(k) history	78 submissions · 78 cleared · 1994-2026

KLS-Martin L.P. is a surgical device manufacturer based in Jacksonville, US. The company specializes in surgical innovation across orthopedic, dental, and neurology device categories. KLS-Martin has received FDA 510(k) clearances from total submissions since its first clearance in 1994. The company maintains active regulatory status, with its latest FDA 510(k) clearance in 2026. Core product areas include orthopedic implants and fixation systems, dental implants and surgical instruments, and neurosurgical devices including cranial implants and expansion systems. Notable r...

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